Pulmonary Hypertension Clinical Trials: What Are Prevailing Patient Experiences in Pulmonary Hypertension Studies?

Informed Consent Form (ICF) For Power Clinical Trial's Pulmonary Hypertension Medical Trial

Date: June 15, 2023

About This Informed Consent Form

Acknowledging your agreement to participate in the study in this document, we have divided the information into two main sections to ensure clarity and understanding. The Patient Information Sheet's first section offers valuable insights into the clinical study, outlining its purpose and your role as a participant. The second part is the Certificate of Consent, which requires your signature to indicate your willingness to participate in the study. Once you have signed the certificate, a copy of the document will be provided for your records.

Part I: Patient Informed Consent Form Sheet

Introduction to the Clinical Trial

We encourage you to engage in a significant medical research study to understand the elements that affect your clinical trial experience fully. We want to know why you joined, stayed, or left the clinical research.

Before deciding, take time to consider this study's benefits. To get more perspectives, talk to friends or doctors.

Recognizing that the permission paperwork may contain unfamiliar medical terminology is crucial. You can ask the research staff to clarify any record terminology ambiguities or confusion.

Our research has been ethically reviewed and follows federal standards that protect human participants. Your participation in this research project could significantly advance medical knowledge.

Purpose of a Clinical Trial on Pulmonary Hypertension

We appreciate your valuable input regarding your involvement in Power's innovative medical trial. By sharing your experiences, you will significantly contribute to our efforts in comprehending the patient characteristics associated with clinical trials for pulmonary hypertension.

As part of this research endeavor, we aim to engage a diverse range of individuals to ensure a comprehensive collection of data regarding their clinical trial experiences. Our objective is to identify the barriers and difficulties that hinder participation in clinical trials and understand the reasons behind withdrawal or discontinuation.

The valuable insights obtained from this study will ultimately benefit individuals diagnosed with pulmonary hypertension who may be invited to participate in medical research in the future.

Exploring Patient Experiences: An Observational Study

Due to the nature of this trial as an observational research study, no new treatment protocol will be suggested. Should you choose to participate in this research project, you will not be required to make any adjustments to how you are already being treated. The only thing that will be different is that the researcher will interview you to obtain information. Other than that, everything else will remain the same. You will not receive a diagnosis from the researcher, nor will they be able to recommend a course of treatment for you. Data collection is the only objective at this point.

Participation Eligibility

To be eligible for this study, you must be currently enrolled in another clinical trial for pulmonary hypertension. Our objective is to understand why you chose to participate in this research and the factors influencing your decision to continue or discontinue the treatment.

We are keen to learn what motivated you to join the study and what considerations determine your determination to remain engaged or opt out. By doing so, we aim to uncover the critical factors influencing patients' decisions in clinical trials for pulmonary hypertension.

Please note that participation in this study is entirely voluntary and optional. Should you decide to participate, your current treatment plan for the other clinical trial will remain unchanged. You have the right to withdraw from the study at any time if you feel uncomfortable, and your decision will not result in the forfeiture of any legal rights.

Comparing Related Pulmonary Hypertension Clinical Trials

While patients with pulmonary hypertension can choose to participate in interventional clinical trials involving specific treatment plans, the clinical trial we invite you to is an observational one. It is designed solely for observational purposes, without requiring enrollment in any treatment plan.

We understand that listing all the available studies on bile duct cancer in this document is impractical. To explore additional opportunities for participation in clinical trials related to pulmonary hypertension, we encourage you to visit clinicaltrials.gov which is a reliable repository for pulmonary hypertension studies. Or, consult Power's website to get detailed information about other ongoing pulmonary hypertension clinical trials that you may consider applying to.

Expectations Regarding the Clinical Trial

If you want to participate in our research, you will be asked to complete a questionnaire every two weeks. Typically, it takes approximately 30 minutes to complete one of these questionnaires. Additionally, we will schedule quarterly check-in conversations with you to maintain contact.

Please keep in mind that even if you must enroll in an interventional clinical trial to participate in our study, our research concentrates solely on observation. It will not affect

your diagnosis or treatment plan for this trial. If you have any queries about the other issue, be sure to get in touch with your healthcare team immediately.

You have complete control over the information you elect to share. You are not required to respond to inquiries that make you uneasy. You can also complete the survey independently or request assistance by having someone read the questions audibly. You may skip any questions you do not desire to respond to.

Your identity will not appear on the survey forms to protect your privacy. We will guarantee the anonymity of all data collected. Please be assured that any information you provide, including personal information, will be treated with the utmost discretion. We will only share it with the research team and safeguard it with encryption, passwords, and anonymity measures. For the safety of patients, we will replace names with numeric identifiers. Additionally, digital permission forms and phone records are handled securely.

More Details on Representation in Clinical Studies

If you want to learn more about diversity and inclusion in clinical trials, check out the following articles:

Duma, Narjust, Jesus Vera Aguilera, Jonas Paludo, Candace L. Haddox, Miguel Gonzalez Velez, Yucai Wang, Konstantinos Leventakos et al. "Representation of minorities and women in oncology clinical trials: review of the past 14 years." *Journal of oncology practice* 14, no. 1 (2018): e1-e10.

Mason, Su, Mahvash Hussain-Gambles, Brenda Leese, Karl Atkin, and Julia Brown. "Representation of South Asian people in randomised clinical trials: analysis of trials' data." *Bmj* 326, no. 7401 (2003): 1244-1245.

Part II: Informed Consent Form

Participation Confirmation from the Patient

I hereby confirm my willingness to participate in a medical research study on patients diagnosed with neuroblastoma As an individual suffering from this condition, I have been chosen to participate in this active clinical trial.

I have thoroughly examined the consent document, engaged in discussions, and had the opportunity to seek clarifications or raise any concerns I might have had. All my queries have been addressed satisfactorily, and I willingly consent to join this study.

I have been furnished with a personal copy of this consent form, which I will keep for future reference. I understand that my participation in this study is entirely voluntary, and I retain the right to withdraw at any point without facing any adverse consequences. Furthermore, I am aware that the research team will uphold the confidentiality of my personal information and ensure the security of all data collected during the study.

Participant's Printed Name: _____

Participants Signature: _____

Statement of the Individual Obtaining Consent from Participants

Special attention was devoted to ensuring that the potential participant grasped the study's intricacies and implications. I invested significant effort in meticulously elucidating the permission form, allowing ample time for the participant to ask any questions they may have had. All inquiries were addressed transparently and to the best of my capability. The participant decided to join the study freely and autonomously, without coercion or undue influence.

The individual has been given a copy of this form.

Name of the Participant (Printed): _____

Participant's Signature::_____

Date: _____
Day/Month/Year